UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,540	12/31/2003	Joel Q. Xue	066243-0240 (141224)	8825

33679 7590 06/13/2007

GE MEDICAL SYSTEM
C/O FOLEY & LARDNER LLP
777 EAST WISCONSIN AVENUE
MILWAUKEE, WI 53202-5306

EXAMINER	
ABRAHAM, SALIEU M	

ART UNIT	PAPER NUMBER
3709	

MAIL DATE	DELIVERY MODE
06/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/749,540	XUE ET AL.	
	Examiner	Art Unit	
	Salieu M. Abraham	3709	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,13-27* is/are rejected.

7)☒ Claim(s) *12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/31/2003 and 04/26/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 3 and 13 are objected to because of the following informality: all claims include language "computed tomography, magnetic resonance, and/or ultrasound".

- "computed tomography, magnetic resonance, and/or ultrasound" should be changed to -- computed tomography, magnetic resonance, or ultrasound --.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 20-21, 25 and 26 are rejected under 35 U.S.C. 102(e) as being unpatentable over Pub. No. US 2003/0093067 A1 to Panescu (Panescu).

In Reference to Claim 20

Panescu teaches a system comprising:

- a processor configured to be communicatively coupled to a probe, the probe being configured to be located in or adjacent to a heart; (see figure 1, reference marks 124 and 126 and sections 0039-0042).
- "memory configured to store: an image of at least a portion of the heart; a first data set pertaining to one or more locations of a heart vector of the heart, the first

data set being spatially correlated with the image;

a second data set pertaining to one or more locations of the heart vector of the heart;

a display configured to display the image and a representation of the probe, the image being registered with the representation of the probe by registering the heart vector from the first data set with the heart vector from the second data set. (see figure 1, reference marks 104, 166, 102 and 126 and sections 0039-0042).

- a display configured to display the image and a representation of the probe, the image being registered with the representation of the probe by registering the heart vector from the first data set with the heart vector from the second data set. (see figure 1, reference marks 106 and 146 and sections 0012-0013).

Note: The memory (structure) depicted in figure 1 of Panescu is configured to store data from a plurality of sources and there is no reason to preclude data sets related to heart vectors. The heart vector data set storage is not limiting on the Panescu structure of the Panescu memory. Furthermore, the display of Panescu has been shown to be capable of displaying a registered probe with image. How this capability is achieved, is also not limiting on the display's capability to display the data once acquired.

In Reference to Claim 21

Panescu has been shown to teach all limitations of 20. Panescu further teaches:

- the system of claim 20, wherein the display is configured to display a map of electrical properties of the heart in conjunction with the image and representation of the probe (see sections 0050 for function of mapping device < device shown by reference mark 142 in figure 1> and 0007 and 0008 for limitation).; also see discussion at end of claim 2 rejection).

In Reference to Claim 25

Panescu teaches: Panescu has been shown to teach all limitations of 20. Panescu further teaches the system of claim 20 "wherein the system is an electrophysiology monitoring system (see abstract, figures 1, 7-9, and sections 0007-0011, 0034, and 0050). The cited areas conform to applicant's definition of an electrophysiology monitoring system in section 0019 of the patent application.

In Reference to Claim 26

Panescu has been shown to teach all limitations of 20. Panescu further teaches that heart mapping data can be spatially correlated with a probe used for electrophysiological study of the heart (see sections 0007 and 0010). Panescu also teaches an embodiment (fourth; see section 0010) whereby two sets of location data can be acquired for guiding probes such as catheters using registered images.

Therefore Panescu anticipates claim 26 because it discloses both structurally and methologically ways to spatially correlate acquired data sets in a specific order. For example, in section 0007 the mapping data is acquired after the imaging data as disclosed applicant . Once again how the data set is acquired does not limit the apparatus or system in spatially correlating the data once it is acquired..

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-11, 13- 19, 22-24 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pub. No. US 2003/0093067 A1 to Panescu (Panescu) in view of US Pat. No. 6,301496 B1 to Reisfield (Reisfield).

In Reference to Claim 1

Panescu teaches a method comprising "acquiring an image pertaining to a heart (see abstract, figure 7A, and sections 0004 and 0007). Panescu further teaches the step of "registering a representation of a probe which is in or adjacent to the heart with the

image (sections 0007 and 0009). However Panescu fails to disclose the step of "registering a representation of a probe which is in or adjacent to the heart with the image using a heart vector of the heart."

Reisfeld teaches the utilization of heart vectors in order to aid in diagnosing cardiac arrythmias (sse abstract annd figures 10-14) and improve heart/cardiac mapping in order to better tag and locate areas with "aberrant electrical pathways and currents within the heart (see column1, lines 14-18, and column 2, lines 7-36).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the step of " "registering a representation of a probe which is in or adjacent to the heart with the image using a heart vector of the heart" of Reisfeld in the image acquisition/probe registration method according to Panescu in order to improve methods for cardiac mapping in order to better locate deficient functional areas of the heart for probe placement in electrophysiological studies (see cloumn 1, lines 14-18, and column 2, lines 7-36,) as explicitly taught by Reisfeld.

In Reference to Claim 2

Panescu in view of Reisfeld has been shown to teach all of the limitations of claim1. Panescu further teaches the step of "further comprising simultaneously displaying the registered image, the registered representation of the probe, and a map of the electrical properties of the heart" (see sections 0050 for function of mapping device <

device shown by reference mark 142 in figure 1> and 0007 and 0008 for limitation).

Because the three-dimesional map described in various sections (see for example 0007 ,0008) of Panescu, present a 3D mapping of locations of irregular electrical heart activity (see section 0050), it follows that these locational mappings constitute mappings of "electrical properties of the heart."

Therefore, Panescu in view of Reisfeld teaches all claim 2 limitations as well.

In Reference to Claims 3 and 4

Panescu in view of Reisfeld has been shown to teach all of the limitations of claim 2. Panescu further teaches the step "wherein the image is acquired using computed tomography, magnetic resonance, and/or ultrasound." (see sections 0008 and at bottom of page1).

Panescu in view of Reisfeld has been shown to teach all of the limitations of claim1. Additionally, Panescu in view of Reisfeld has been also been shown to teach the step "wherein the organ or structure inside the body comprises a heart and the bodily cycle is a cardiac cycle" as discussed above in claim 1 (also see Panescu section 0007 and Reisfeld column 3, lines 45-57).

In Reference to Claim 5

Panescu in view of Reisfeld has been shown to teach all of the limitations of claim1. Panescu further teaches the step "wherein the probe is configured to sense

electrical information pertaining to the heart." (see section 0050).

In Reference to Claim 6

Panescu in view of Reisfeld has been shown to teach all of the limitations of claim1. Reisfeld further teaches the utilization of body surface electrodes in his system of vector mapping of the heart and, therefore, this addresses applicant's step "wherein the heart vector is determined using data acquired from a body surface lead system." (see column 17, lines 1-5).

In Reference to Claim 7

Panescu in view of Reisfeld has been shown to teach the limitations of claim1:

a) acquiring an image of or pertaining to a heart; and

b) registering a representation of a probe which is in or adjacent to the heart with the image using a heart vector of the heart.

Panescu further teaches the acquisition of multiple data sets from the heart from , to include location specific data (see sections 0007-0010 and 0059-0061), in order to register a representation of a probe along with an image of the heart (see sections 0006 and 0007). Panescu further teaches that two data sets can be acquired: 3D image data and 3D (deficient electrical areas) mapping of the heart or other internal body organ of study (see section 0007 at top of page 1). Also, two respective location

data sets can be acquired with/inaddition to the image and mapping data in order to correlate overall heart and heart defective area locations(see fourth embodiment in section 0010 at bottom of page 1). However, Panescu fails to teach the probe and heart image registration and mapping (e.g. the 3D heart image and map location data) being accomplished through the use of heart vectors or more specifically according to claim 7:

-- "acquiring a first data set pertaining to one or more locations of a heart vector of the heart, the first data set being spatially correlated with the image;
acquiring a second data set pertaining to one or more locations of the heart vector of the heart;
registering a representation of a probe with the image by registering the location of the heart vector from the first data set with the location of the heart vector from the second data set."

As described before, Reisfeld teaches of 3D vector mapping of internal body organs such as the heart in order to better locate deficient functional areas of the heart for probe placement in electrophysiological studies (see column 1, lines 14-18, and column 2, lines 7-36,).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have substituted the step of 3D vector mapping of the heart of Reisfeld in the method of mapping the (dual) heart and heart map location data sets of Panescu in

order to improve the locating of "aberrant electrical pathways" in the heart by medical personnel as explicitly taught by Reisfeld.

In Reference to Claim 8

Panescu in view of Reisfeld has been shown to teach all of the limitations of claim7. Reisfeld further teaches the step wherein "the registering step comprises registering the heart vector from the first data set with the heart vector from the second data set for at least a portion of a cardiac cycle" (see column 17, lines 37-47). Therefore, Panescu in view of Reisfeld further teaches all claim 8 limitations.

In Reference to Claim 9

Panescu in view of Reisfeld has been shown to teach all of the limitations of claim 8. Reisfeld further teaches that a plurality of locations related to vector mapping of the heart "are determined at a common point in the cardiac cycle, preferably at end diastole." Because end-diastole includes a portion of the QRS complex, Reisfeld therefore also teaches the step "wherein the portion of the cardiac cycle comprises at least a portion of the QRS portion (see column 17, lines 28-37).
Therefore Panescu in view of Reisfeld further teaches all claim 9 limitations as well.

In Reference to Claim 10

Panescu in view of Reisfeld has been shown to teach all of the limitations of claim 8. Panescu further teaches the step "wherein the probe is configured to sense the

electrical properties of the heart" (see section 0050).

Therefore Panescu in view of Willis further satisfies all claim 10 limitations as well.

In Reference to Claim 11

Panescu in view of Reisfeld has been shown to teach all of the limitations of claim 8. Panescu further teaches the step "wherein the image is at least a three dimensional image". (see sections 0006 and 0007).

Therefore Panescu in view of Reisfeld further teaches all claim 11 limitations as well.

In Reference to Claim 13

Panescu in view of Reisfeld has been shown to teach all of the limitations of claim 8. Furthermore, Panescu also teaches the step "wherein the image comprises one or more images obtained using computed tomography, magnetic resonance, and/or ultrasound" (see section 0008).

Therefore Panescu in view of Reisfeld further teaches all claim 13 limitations as well.

In Reference to Claims 14 and 15

Panescu in view of Reisfeld has been shown to teach all of the limitations of claim 8. Furthermore, Reisfeld also teaches the step "wherein the first and second data sets are acquired using a body surface lead system" (see column 17, lines 1-5). Probe 202 provides continuos acquisition of heart electrophysiological data.

Therefore Panescu in view of Reisfeld further teaches all claim 14 and 15 limitations as well.

In Reference to Claim 16

The combination of Panescu and Reisfeld disclose all claim 16 limitations except "adjusting the size and/or position of the image using a heart vector of the heart. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to have included the step of adjusting the size and/or position on a portion of the image in order to optimize the image display and data analysis (see MPEP 2144).

In Reference to Claim 17 and 18

See rejections in claim 1-6.

In Reference to Claim 22

Panescu has been shown to teach all of the limitations of claim 20.

However, Panescu fails to teach the system "wherein the first and second data sets are obtained using a plurality of electrocardiogram leads.

Reisfeld teaches of 3D heart vector mapping employing a plurality of electrocardiogram leads (see column 17, lines 1-5) in order to further analysis of the "functioning heart" and allow a physician to "decide on a required treatment accordingly" (see column 18, lines 45-52).

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have included the step of obtaining the data sets for heart vector mapping using a plurality of electrocardiogram leads of Reisfeld in the system of Panescu in order to provide further analytical tools the analysis of heart function and allow physicians to decide on appropriate and customized treatment protocols for correcting defective electrophysiological conditions of the heart explicitly taught by Reisfeld (see

abstract and column 18, lines 45-52) .

In Reference to Claim 23

Panescu has been shown to teach all of the limitations of claim 20 (e.g. a system capable of acquiring heart images and registering a probe representation with it based on using heart vectors). Furthermore, Panescu in view of Reisfeld has been shown to teach the method "wherein the representation of the probe is registered with the image by registering the heart vector from the first data set with the heart vector from the second data set for at least a portion of the cardiac cycle" (see column 17, lines 37-47). Therfore, since Panescu in view of Reisfeld teaches both the apparatus and method for the step "wherein the representation of the probe is registered with the image by registering the heart vector from the first data set with the heart vector from the second data set for at least a portion of the cardiac cycle" (see column 17, lines 37-47), it further teaches all claim 23 limitations.

In Reference to Claim 24

Panescu has been shown to teach all of the limitations of claim 20 (e.g. a system capable of acquiring heart images and registering a probe representation with it based on using heart vectors). Furthermore, Panescu in view of Reisfeld has been shown to teach the method "wherein the portion of the cardiac cycle comprises at least a portion of the QRS segment" (see earlier claim 9 rejection).

Therfore, since Panescu in view of Reisfeld teaches both the apparatus and method

for the step "wherein the portion of the cardiac cycle comprises at least a portion of the QRS segment" (see earlier claim 9 rejection), it further teaches all claim 24 limitations.

In Reference to Claim 27

Panescu has been shown to teach all of the limitations of claim 20.

However, Panescu fails to teach the step "wherein the first and second data sets are acquired using a body surface lead system. As described before, Reisfeld teaches a method "wherein the first and second data sets are acquired using a body surface lead system (see claim 14 rejection). Therfore, since Panescu in view of Reisfeld teaches both the apparatus and method for the step "wherein the first and second data sets are acquired using a body surface lead system", it further teaches all claim 27 limitations (see claim 14 rejection).

Allowable Subject Matter

5. Claim 12 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ben-Haim et al. , Pearlman, Beatty et al., Xue et al., Chenal et. al., Reisfeld et. al., Osadchy et al., Panescu et al. and Nolte et al. have been included because they all encompass MR, CT or ultrasound imaging systems and methods that

are strongly related to electrophysiology studies and applications as described by the applicant. Additionally, Pearlman has been included because his invention involves imaging methodology and apparatus that reconstructs a single composite image or image set from two images or image sets at different time points. This is done in order to enhance or more accurately display any event(s) that transpired between the image acquisition time points.

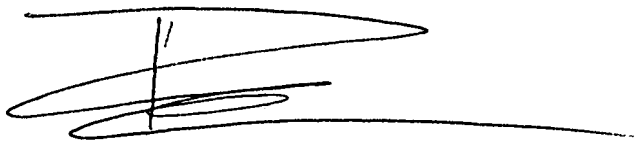
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Salieu M. Abraham whose telephone number is (571) 270-1990. The examiner can normally be reached on Monday through Thursday 8:30 am - 6:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kenneth Bomberg can be reached on (571) 272-4922. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SA

6/11/07



THAO X. LE
PRIMARY PATENT EXAMINER